PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference Sch/svk/KVLMT-1pct	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/NL 03/00414	International filing date *(day/month/year)* 05.06.2003	Priority date *(day/month/year)* 06.06.2002
International Patent Classification (IPC) or both national classification and IPC A61F5/01		
Applicant KVLMT B.V. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the International application

Date of submission of the demand	Date of completion of this report
31.12.2003	30.04.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Lega D'Incecco, A.M. Telephone No. +49 89 2399-2339

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00414

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-7 received on 31.12.2003 with letter of 12.11.2003

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☒ the claims, Nos.: 8,9

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-7
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

   see separate sheet

V.

1. An orthopaedic device according to the preamble of claim 1 is known from document US-A-6 362 387 (D1).

   The characterising feature of claim 1 provides a low friction on the fastening means and prevents that the device shifts out of its nominal position.

   Therefore the subject-matter of claim 1 is novel (Article 33(2) PCT) and involves an inventive step (Art. 33(3) PCT).

2. Claims 2-7 relate to preferred embodiments of the subject-matter of claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

3. Industrial applicability is self evident (Art. 33(4) PCT)

4. However, the application does not meet the requirements of the PCT in the following respects:

4.1 Claim 1 is not clear (article 6 PCT), since the expressions "in particular", "for example" "such as", "for instance", "optional" and "such as" have no limiting effect on the scope of the claim, that is to say, that the feature following any such expression is to be regarded as entirely optional (see PCT Guidelines, Chapter III-4.6).

4.2 The expression "at least more or less" used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

4.3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

4.4 The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

4.5 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

CLAIMS

1. Orthopaedic device, in particular a prosthesis or an orthosis, for the purpose of replacing respectively supporting the function of at least one part of a human limb with a pivotable joint, for example a leg with a knee or an arm with an elbow, on either side of which joint there extend respective limb parts, such as a lower leg and an upper leg respectively a lower arm and an upper arm, which device comprises:

a structure comprising two substantially rigid parts, for instance two rods, which parts are coupled to each other by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part,

wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of the pivot axis zone of the relevant joint,

characterized in that

the fastening means are at least partly provided with friction-reducing means on at least the side to be brought into contact with the relevant limb part.

2. Device as claimed in claim 1,

characterized in that

the friction-reducing means comprise at least one flexible pillow filled with a viscous liquid, for example a gel.

3. Device as claimed in claim 1,

characterized in that

the friction-reducing means comprise a layer of suitable plastic, for instance PE (polyethylene) or PTFE (polytetrafluoroethylene).

4. Device as claimed in claim 1,

characterized in that

the friction-reducing means comprise a number of freely rotatable elements, such as rollers or balls.

5. Device as claimed in claim 1,

characterized in that

said structure is provided on only one side with hinge means.

6. Device as claimed in claim 1,

characterized in that

the fastening means comprise divisible flexible rings with adjustable periphery.

7. Device as claimed in claim 1,

characterized by

at least one additional ring with adjustable periphery, which ring is connected or can be connected to a structural part and is free of friction-reducing means.

8. Device as claimed in claim 7,

characterized in that

the additional ring is coupled or can be coupled to a ring provided with friction-reducing means by means of an optionally adjustable tensioner extending in longitudinal direction, for example a cord, a draw spring or an elastic strap.

9. Device as claimed in claim 1,

characterized in that

the device is a knee orthosis.

10. Device as claimed in claim 1,

characterized in that

the device is a knee-ankle-foot orthosis.

AMENDED CLAIMS

[Received by the International Bureau on 11 November 2003 (11.11.2003); original claims 1-10 replaced by amended claims 1-7 (2 pages)]

1. Orthopaedic device, in particular a prosthesis or an orthosis, for the purpose of replacing respectively supporting the function of at least one part of a human limb with a pivotable joint, for example a leg with a knee or an arm with an elbow, on either side of which joint there extend respective limb parts, such as a lower leg and an upper leg respectively a lower arm and an upper arm, which device comprises:

a structure comprising two substantially rigid parts, for instance two rods, which parts are coupled to each other by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part,

wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of the pivot axis zone of the relevant joint,

said fastening means being at least partly provided with friction-reducing means on at least the side to be brought into contact with the relevant limb part,

characterized in that

the friction-reducing means comprise a number of freely rotatable elements, such as rollers or balls.

2. Device as claimed in claim 1,

characterized in that

said structure is provided on only one side with hinge means.

3. Device as claimed in claim 1,

characterized in that

the fastening means comprise divisible flexible rings with adjustable periphery.

4. Device as claimed in claim 1,

characterized by

at least one additional ring with adjustable periphery, which ring is connected or can be connected to a structural part and is free of friction-reducing means.

5. Device as claimed in claim 4,

characterized in that

the additional ring is coupled or can be coupled to a ring provided with friction-reducing means by means of an optionally adjustable tensioner extending in longitudinal direction, for example a cord, a draw spring or an elastic strap.

6. Device as claimed in claim 1, characterized in that the device is a knee orthosis.

7. Device as claimed in claim 1, characterized in that the device is a knee-ankle-foot orthosis.